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10/025,958	12/18/2001	James O. Gilkerson	279.209US2	2116

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	PAPER NUMBER
3762	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/025,958	GILKERSON ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is "wherein the clinical rhythm is associated with two or more available detection enhancements" in combination with the other elements in the claims (or "at least two...enhancements" in claim 18). The original specification used the range of "one or more" or "at least one" available detection enhancement and the new amended language of "two or more" or "at least two" is a new range not originally disclosed. This rejection is related to new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 18, line 8, "the at least one available detection enhancement" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Snell (5716382). Snell discusses the selection of the clinical rhythm as the selection of atrial fibrillation (e.g. figure 5) and further discusses the plurality of detection enhancements (set of rules for when to deliver therapy) as the different ways that therapy is required (e.g. figure 6, such as when intermittent AF). Snell further discloses that one or multiple recommendations will be made by the rule engine of which the physician can choose from (e.g. col. 6, lines 15-40) and therefore provides the claimed "user-provided selection to modify the selection of the at least one detection enhancement".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-21, 30-34, 37, and 39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Snell. Snell discloses that the display displays different questions and recommendations and parameters based upon the answered questions. Since the screen will be updated with the questions and parameters, each is considered a different screen/layer. In addition, the system uses a rules engine, such as deduction oriented or antecedent consequence, which is considered artificial intelligence since it is not calculated by a human and/or it imitates human intelligence. In addition, it is noted that the selection of AF is the capability to select a number (one) of tachyarrhythmia zones and it allows the selection of the detection enhancement that inhibits therapy for AF since if "no" is chosen for AF it will not address AF.

In the alternative, Snell discloses the claimed invention except for the screens/layers and the use of artificial intelligence to select a detection enhancement. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the computer and display system and method as taught by Snell, with the screen/layers and the use of artificial intelligence to select a parameter, such as a detection enhancement, since it was known in the art that computer and display systems and methods use different screens and layers to provide information in an easy to understand format that is not crowded/busy with other information and

since it was known to use artificial intelligence to select a parameter to allow the system to be automated and reduce the human interaction with the computer and results.

Claims 22, 23, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell as applied to claims above. Snell discloses the claimed invention except for the indicator indicating the changed parameter has been programmed, the warning indicator for parameter interaction, and the screen providing an ECG display. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart computer and display system and method as taught by Snell, with the indicator indicating the changed parameter has been programmed, the warning indicator for parameter interaction, and the screen providing an ECG display since it was known in the art that heart computer and display systems and methods use: an indicator indicating the changed parameter has been programmed to allow the physician to know the parameter has been changed so he does not have to wonder if it has been changed; a warning indicator for parameter interaction to allow the physician to change a parameter if there is an interaction that he did not know about or realize; and the screen providing an ECG display to allow the physician to monitor the sensing by the electrodes and how the system functions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-23 and 30-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/369142 and over claims 1-27 of 11/379742. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application's claims are narrower and meet the limitations of this application's broader claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the copending application's claims the recommendation of a detection enhancement, a module to allow the user to select another enhancement, the multiple layers/screens for displaying the data, a changed parameter indicator, a warning indicator, and a ECG screen since it would provide an automated system that takes the guess work out of choosing an enhancement but that also allows the physician to choose what he considers a better treatment/option and since it would provide multiple layers/screens for displaying the data to provide information in an easy to understand format that is not crowded/busy with other information and: an indicator indicating the changed parameter has been programmed to allow the physician to know the parameter has been changed so he does not have to wonder if it has been changed; a warning indicator for parameter interaction to allow the physician to change a parameter if there is an interaction that he did not know about or realize;

and the screen providing an ECG display to allow the physician to monitor the sensing by the electrodes and how the system functions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 14-23, 30-34, and 37-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6493579. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are narrower and meet the limitations of this application's broader claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the patented claims the recommendation of a detection enhancement, a module to allow the user to select another enhancement, the multiple layers/screens for displaying the data, a changed parameter indicator, a warning indicator, and a ECG screen since it would provide an automated system that takes the guess work out of choosing an enhancement but that also allows the physician to choose what he considers a better treatment/option and since it would provide multiple layers/screens for displaying the data to provide information in an easy to understand format that is not crowded/busy with other information and: an indicator indicating the changed parameter has been programmed to allow the physician to know the parameter has been changed so he does not have to wonder if it has been changed; a warning indicator for parameter interaction to allow the physician to change a parameter if there is an interaction that he did not know about or realize; and the screen

providing an ECG display to allow the physician to monitor the sensing by the electrodes and how the system functions.

Claims 14-23, 30-34, and 37-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 16 of U.S. Patent No. 6522925. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are narrower and meet the limitations of this application's broader claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the patented claims the recommendation of a detection enhancement, a module to allow the user to select another enhancement, the multiple layers/screens for displaying the data, a changed parameter indicator, a warning indicator, and a ECG screen since it would provide an automated system that takes the guess work out of choosing an enhancement but that also allows the physician to choose what he considers a better treatment/option and since it would provide multiple layers/screens for displaying the data to provide information in an easy to understand format that is not crowded/busy with other information and: an indicator indicating the changed parameter has been programmed to allow the physician to know the parameter has been changed so he does not have to wonder if it has been changed; a warning indicator for parameter interaction to allow the physician to change a parameter if there is an interaction that he did not know about or realize; and the screen providing an ECG display to allow the physician to monitor the sensing by the electrodes and how the system functions.

Response to Arguments

Applicant's arguments filed 7/26/07 have been fully considered but they are not persuasive. The argument that the '925 patent contains more limitations, such as a button on the display screen, than the application's claims and the button has not been addressed in the double patenting analysis is not persuasive since both sets of claims are "comprising" open ended claims and do not preclude the use of additional structure. In addition, the test for double patenting is whether the patented claims meet/anticipate (or are obvious variants of) the application's claims and not the other way around. Since the patented claims (and copending application's claims) are narrower and meet the limitations of this application's claims, the double patenting rejection was properly applied.

The argument that the claims use the terms "clinical rhythm, detection enhancement, and parameter" is correct, although no specific definition has been set forth in the specification for these terms and therefore they have been given their broadest reasonable interpretation as described above in the rejections. The argument that Snell fails to show a selected clinical rhythm and at least one parameter forming at least a portion of a detection enhancement is incorrect since Snell programs the implantable device with "at least one parameter" since he programs at least the mode of the IMD. The argument that the office action improperly equates parameters and detection enhancements is not persuasive. The 103 rejection on page 4, line 7 of the previous office action was not equating the "claimed" parameter to a detection enhancement, but the general definition of a parameter (e.g. a factor that defines a system, a limiting factor, a notable characteristic, etc), "such as a detection enhancement", and how artificial intelligence can be used to select a parameter/detection enhancement.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762
10/11/07

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